

# Exhibit I



Deposition of:  
**Rebecca Betensky , Ph.D.**

*July 26, 2016*

In the Matter of:  
**Clare-Austin vs. C.R. Bard**

**Tiffany Alley, A Veritext Company**

1075 Peachtree St. NE , Suite 3625

Atlanta, GA, 30309

800.808.4958 | [calendar-ga@veritext.com](mailto:calendar-ga@veritext.com) | 770.343.9696

1 Q. But it was clear, even if you didn't  
2 perform the exact calculations, it was clear that  
3 the frequency of these reported adverse events was  
4 not huge; correct?

5 MR. MANKOFF: Object to form.

6 A. Correct, relative to the reported sales  
7 numbers and the reported events, that's correct.

8 Q. Now, you've been using and we've been using  
9 interchangeably as you said reported risk ratio,  
10 that term, with reported relative risk. How does a  
11 reported relative risk differ from a relative risk?

12 A. So the qualifier "reported" is important,  
13 and that's indicating that the data are coming from  
14 reports, and are not being derived from a  
15 beautifully run and designed experiment like a  
16 clinical trial, in which there's perfect follow-up  
17 and in which it's really a true experiment.

18 So the "reporting" qualifier is there to  
19 say and to suggest that these are numbers that are  
20 reported. These are based on reports.

21 Q. And that's different from a true relative  
22 risk; correct?

23 A. A relative risk, which is what the target  
24 is, which is what would be of interest, wouldn't be  
25 entangled with issues around reporting.

1 Q. And we don't know whether that occurred in  
2 this instance with this particular data set, do we?

3 MR. MANKOFF: Object to form.

4 A. We don't whether what occurred?

5 Q. Underreporting or overreporting. You said  
6 it could lead to it.

7 A. No --

8 Q. We don't know whether it led to either way  
9 in this case, do we?

10 A. I'm sorry; I said --

11 MR. MANKOFF: Just let the court  
12 reporter catch up.

13 Object to form.

14 A. Okay. I didn't say anything about  
15 overreporting. What I said was overestimates. So  
16 these data could -- they provide an estimate, we  
17 call it the reporting risk ratio. And this estimate  
18 could be an overestimate or it could be an  
19 underestimate.

20 Q. Okay, and I stand corrected. Let me  
21 rephrase that question.

22 And we cannot say, sitting here today,  
23 whether the reported relative risk that you  
24 calculated overestimates or underestimates in this  
25 particular data set, can we?

1     respect to that is just looking at the sales data  
2     over time across ten years of time for some  
3     products, and less so for others because they were  
4     removed from the market earlier. The sales data  
5     seems pretty constant month by month, which is the  
6     granularity at which I have the data.

7             So I would imagine that these are  
8     expensive devices and nobody wants too many of them  
9     sitting on the shelf; and so over time, institutions  
10    or physicians learn better how to estimate their  
11    needs, and so that wouldn't be a very big problem.

12            So I did also address that through one  
13    of my sensitivity analyses, and just assumed -- or  
14    just considered what would happen if I discounted  
15    the sales data by 20 percent and just assumed that  
16    20 percent are sitting on the shelf and 80 percent  
17    are implanted, and I obtained comparable results to  
18    when I didn't do that discounting.

19            Q. Other limitations?

20            A. So another limitation is that these are  
21    crude estimates of risk and reflect different times  
22    of exposure to devices, partly due to when the SNF,  
23    for example, was available prior to the start time  
24    of 2000; also reflecting the permanent versus  
25    retrievable issue.